UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATE OF NEW JERSEY, ex rel. STEVE GREENFIELD, et al., Plaintiffs,	CIVIL NO. 12-522(NLH)(AMD)
v.	**OPINION**
MEDCO HEALTH SYSTEMS, INC., ACCREDO HEALTH GROUP, INC., and HEMOPHILIA HEALTH SERVICES, INC., Defendants.	

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HILLMAN, District Judge

This qui tam action concerns claims by plaintiff, Steve Greenfield, that defendants violated the federal False Claims Act ("FCA") relating to pharmaceutical products for hemophilia.[1] Currently before the Court are the parties' competing motions for summary judgment in their favor.[2] For the reasons expressed

[1] A private individual, otherwise known as a relator, may bring a civil action in the name of the United States to enforce § 3729 of the FCA and may share a percentage of any recovery resulting from the suit. U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011) (citing 31 U.S.C. § 3730(b) & (d)). Because it was filed as a qui tam action, the entire case was filed under seal in order to allow the United States and interested states to investigate whether they wished to intervene in the action and prosecute plaintiff's claims on their behalf. See 31 U.S.C. § 3730(b)(2). Neither the United States government nor any of the states listed in the complaint chose to intervene in the action. Accordingly, the complaint was unsealed, and from that point on the case has been publically accessible.

[2] Also pending are pre-trial motions in limine and motions to seal relative to the parties' summary judgment motions and motions in limine. Because the Court finds that the subject documents of the parties' motions to seal meet the requirements

below, defendants' motion will be granted, and plaintiff's motion will be denied.

BACKGROUND

The allegations advanced by plaintiff against defendants, Medco Health Solutions, Inc.,[3] Accredo Health Group, Inc. ("Accredo"), and Hemophilia Health Services, Inc. ("HHS"), have been detailed comprehensively in the Court's prior two Opinions resolving defendants' motions to dismiss. (Docket No. 42 and 50.) The Court incorporates into this Opinion the recitations of the background of this case from the previous Opinions.

Briefly summarized, plaintiff contends that in his capacity as an area vice-president of Accredo, he learned of defendants' fraudulent practices related to their efforts to maintain and increase sales of their products to treat hemophilia.[4] Because

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of Local Civil Rule 5.3(c), the motions to seal will be granted. (Docket No. 107, 113, 117, 128, 133.) As a result of this Opinion, the motions in limine are now moot, and will be denied accordingly. (Docket No. 118, 120, 122, 143.)

[3] Medco Health Solutions, Inc. was improperly pled as "Medco Health Systems, Inc."

[4] Hemophilia is a rare bleeding disorder, and those with the disorder have little or no "clotting factor." Treatment for hemophilia is typically either "on-demand," where a patient receives factor replacement therapy to stop a bleed, or "prophylactic," where a patient receives factor replacement therapy to prevent a bleed. Clotting factor products are expensive, with the annual cost for the treatment of one patient

hemophilia treatment is very expensive, New Jersey law requires health benefit providers to contract with state-authorized hemophilia treatment centers to provide hemophilia patients with their necessary treatment regimen.

The Hemophilia Association of New Jersey, Inc. ("HANJ") was created to coordinate and provide treatment to hemophilia patients. HANJ is a tax exempt entity that, through grants, funds referral entities and makes recommendations to the state for competitive providers. HANJ formed Hemophilia Services, Inc. ("HSI"), also a tax exempt organization, which works with hemophilia treatment centers (HTCs), insurers, and participating home care vendors to provide case management services for the hemophilia population in New Jersey. HSI receives charitable donations, which it grants to HANJ, and HANJ provides insurance and other financial assistance to individuals with hemophilia (hereinafter, HANJ and HSI will be referred collectively as HANJ/HSI).

Plaintiff claims that Medco, through Accredo and HHS, made charitable contributions in amounts of $175,000 to $500,000 or more to HSI/HANJ from 2007 through 2011, with the intent to buy, influence, and induce referrals to defendants. Plaintiff

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ranging from $50,000 to $100,000 or more.

contends that this scheme violates the FCA because many of defendants' hemophilia customers referred by HANJ/HSI through kickbacks in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) ("AKS") are recipients of federally funded health benefit programs, such as Medicare and Medicaid, and when defendants made claims to the government for payment, they falsely certified their compliance with the AKS.[5]

Both plaintiff and defendants have moved for summary judgment in their favor on plaintiff's claims.

DISCUSSION

A. Subject matter jurisdiction

This Court has jurisdiction over plaintiff's federal claims under 28 U.S.C. § 1331.

B. Standard for Summary Judgment

Summary judgment is appropriate where the Court is satisfied that the materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, admissions, or interrogatory answers, demonstrate that there is no genuine

[5] Plaintiff's complaint alleged a second part of the alleged scheme, which concerned excessive gifts: once the charitable donations have funneled patients to defendants' products, defendants ensure the hemophilia patients' continued use of these products by providing them with excessive gifts. Plaintiff has not pursued that part of his claim.

issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986); Fed. R. Civ. P. 56(a). If review of cross-motions for summary judgment reveals no genuine issue of material fact, then judgment may be entered in favor of the party deserving of judgment in light of the law and undisputed facts. See Iberia Foods Corp. v. Romeo Jr., 150 F.3d 298, 302 (3d Cir. 1998) (citation omitted).

C. Analysis

The United States Supreme Court recently considered the parameters of an FCA claim under the same theory presented by plaintiff here.

> The False Claims Act, 31 U.S.C. § 3729 et seq., imposes significant penalties on those who defraud the Government.[6] . . . According to the ["implied false certification"] theory, when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim "false or fraudulent" under § 3729(a)(1)(A). . . .
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> We first hold that, at least in certain circumstances, the implied false certification theory can be a basis for liability. Specifically, liability can attach when the defendant submits a claim for payment that makes specific

[6] The False Claims Act imposes civil liability on "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

> representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading.
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> We further hold that False Claims Act liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. . . . What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision. A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.

Universal Health Services, Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 1995–96 (2016).

In this case, plaintiff contends that defendants submitted false claims for payment from the United States government because the defendants falsely certified their compliance with the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) ("AKS").[7] Plaintiff contends that defendants' actions violate the FCA because: (1) many hemophilia patients, having been referred through and induced by illegal kickbacks to use defendants'

[7] Plaintiff is not asserting an independent claim under the AKS. The AKS is a criminal statute that does not provide for a private cause of action. If an entity falsely certifies its compliance with the AKS, that false certification can serve as a basis for a civil FCA violation. See 31 U.S.C. §§ 3729–3733.

products, are recipients of federal Medicare and Medicaid assistance, (2) federal funds therefore pay defendants for these illegally procured prescriptions, (3) in order to be paid from government funds, defendants have to certify that they have complied with the anti-kickback laws (on Provider Agreement CMS Form 855s),[8] and (4) defendants have presented claims to the government for reimbursement knowing that they violated the anti-kickback laws.

In other words, plaintiff contends that the government would not have paid defendants' claims for reimbursement of hemophilia treatment products if it had known that defendants obtained those patients by giving HANJ/HSI "donations" in exchange for the referral of those patients to defendants' products, in violation of the AKS.

It is undisputed that HANJ/HSI depends upon contributions from the providers of hemophilia products, such as defendants,

[8] Provider Agreement CMS Form 855s provides, "I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare."

to fund insurance programs and HTCs for its members, and it is undisputed that HANJ/HSI is a veritable bulldog in its efforts to secure those donations. HANJ/HSI members are free to choose from any provider for their hemophilia treatment products, but HANJ/HSI maintains a group of preferred providers based on the amount of the providers' donations to HANJ/HSI. On its website, HANJ/HSI lists the preferred providers with links to those providers' websites for the convenience of HANJ/HSI members.

In 2009 and 2010, defendants reduced their donation to HANJ/HSI significantly from $500,000 to $175,000,[9] and HANJ/HSI was aggressive in its tactics to increase defendants' donation amount. HANJ/HSI informed its members of the ramifications of defendants' reduced donations – namely, HANJ/HSI's inability to fund the insurance programs for its members – and HANJ/HSI asked its members to contact defendants to voice their concerns. Seventy-five members did so. Defendants also began to lose customers as a result. In 2011, defendants state that in an effort to stay in the good graces of HANJ/HSI and to maintain

[9] Defendants relate that the reduced funding was a result of budget constraints. Plaintiff contends it was because of compliance concerns. The impetus for the reduced funding is not relevant to the Court's ultimate resolution of plaintiff's claims.

its customers, defendants determined to restore their donation to HANJ/HSI to $350,000 in 2012.

Plaintiff claims that defendants' charitable donations were actually prohibited remuneration under the AKS because they were intended to induce referrals of hemophilia patients.[10] Plaintiff claims that this amounts to a violation of the FCA because defendants' AKS violation resulted in payments to defendants from the federal government for those members who were insured under the federal health care programs.

To prove his FCA claim, plaintiff must pass two hurdles. First, plaintiff must establish that defendants violated the AKS through its alleged quid pro quo arrangement with HANJ/HSI. Second, plaintiff must show that as a result of defendants' AKS violation, defendants received payment from the federal government.[11]

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[10] As discussed below, plaintiff alleges that in addition to helping fund insurance for HANJ members, defendants' donations also went directly to HTCs in the form of grants.

[11] To establish a prima facie FCA violation under § 3729(a)(1), a plaintiff must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 304-05 (3d Cir. 2011) (citations omitted). On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub.L. No. 111–21, 123 Stat. 1617 (2009), which amended the FCA

A great deal of the parties' briefing focuses on the nature of defendants' donations to HANJ/HSI. Plaintiff contends that defendants essentially paid HANJ/HSI to refer its members to defendants for their hemophilia treatment needs, which is a clear violation of the AKS. Unsurprisingly, defendants maintain that their donations to HANJ/HSI were indeed charitable, and HANJ/HSI's categorization of defendants as a preferred provider with website links to their products does not constitute an illegal quid pro quo arrangement.

The Court, however, does not need to delve into the relationship between HANJ/HSI and defendants and determine whether it violates the AKS. Even accepting that plaintiff has met his first hurdle in proving his FCA claim,[12] plaintiff has

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and re designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B).

[12] HANJ/HSI's efforts to fund its insurance programs and support HTCs appear to be more like a worthy-cause extortion scenario rather than a mutual back-scratching scheme. As an initial matter, in order to qualify as a provider approved by HANJ/HSI, HANJ required a provider to donate an "entry-level pledge" of at least $5,000 a month to HANJ/HSI. As a provider increased its profits, HANJ/HSI required more of a donation. When defendants reduced their funding from $40,000 a month to $15,000 a month, that loss of funding significantly affected HANJ/HSI's programs. In addition to asking defendants to reconsider, HANJ/HSI engaged in an aggressive countermeasure by asking its members to directly contact defendants to share their concerns, and not-so-subtly suggest that the members should switch providers so that

not surmounted the second.

The Court twice previously observed that the key fact plaintiff must establish to prevail on his FCA claim is the link between defendants' alleged quid pro quo arrangement and payment from the federal government. The Court dismissed plaintiff's first complaint because plaintiff failed to satisfy Rule 9(b), finding, "Accepting as true that defendants' charitable contributions to HANJ/HSI were intended to induce referrals to defendants' hemophilia treatment products, and that defendants' actions demonstrated prohibited control over the charity's use of its donations, the facts pleaded in plaintiff's complaint are not sufficient, under his Rule 9(b) burden, to show that any of those contributions are tied to federal funds. To the contrary, the quid pro quo scheme between HANJ/HSI and defendants alleged by plaintiff appear to demonstrate that defendants' contributions were used by HANJ/HSI to avoid the need to avail themselves of any federal benefits program." (Docket No. 42, Op. at 17.)

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defendants would experience the economic consequences of their donation reduction. Even though defendants' higher donations to HANJ/HSI resulted in more customers to defendants, if defendants did not make charitable donations to HANJ/HSI, effectively they would have little business in New Jersey from privately insured HANJ/HSI members.

The Court permitted plaintiff to file an amended complaint – his third amended complaint - which the Court found was sufficiently beefed up to satisfy Rule 9(b) and the Foglia v. Renal Ventures Management, LLC, 754 F.3d 153, 155-56 (3d Cir. 2014) pleading standard. (Docket No. 50.) The Court noted that in his newest complaint, plaintiff slightly shifted focus to the goodwill generated by defendants' donations, and the part of this claim that was actionable was that the charitable donations - or kickbacks - illegally induced HANJ to refer patients to defendants' products, defendants tracked these patients to secure their continued use of defendants' products through excessive gifts, and there was evidence that some of these patients were Medicaid and Medicare recipients. (Docket No. 50 at 21 n.9.)

Discovery, however, has not yielded the evidence to support those claims. As a primary matter, and noted above, see supra note 5, since filing his fourth amended complaint, plaintiff has not pursued as a part of defendants' alleged kickback scheme his AKS theory relating to excessive gifts. Thus, plaintiff's FCA claim rests on the theory that defendants' donations to HANJ/HSI to fund insurance for its members, as well as support the operation of HTCs, were in exchange for HANJ/HSI's and the HTCs'

referral of patients to defendants' products, which are violations of the AKS.

The evidence in the record shows that from 2008 to 2012, defendants billed the federal government for twenty-four hemophilia patients, resulting in 897 invoices submitted to the government for payment in the amount of $39,137,649.00.[13] This data does not, however, show that any of these twenty-four patients were referred from HANJ/HSI or an HTC as a result of defendants' donations.

Plaintiff argues that because defendants violated the AKS in their quid pro quo arrangement with HANJ/HSI, any and all claims submitted to the government for hemophilia patients, regardless of how the patients came to be customers of defendants, violate the FCA because defendants certified their compliance with the AKS for each of those claims. Plaintiff's argument is too broad a stroke. Instead, plaintiff must show

[13] This data comes from plaintiff's expert report. (Docket No. 109-4 at 5-8.) Defendants' expert presents essentially the same numbers, except his report accounts for three patients who are covered by Federal BlueCross/Blue Shield, which plaintiff's expert does not classify as a federally funded health plan, like Medicare or Medicaid. Defendants' expert also tallies 894 claims submitted, resulting in charges of $39,186,246.54 and payments totaling $24,900,184.03. (Docket No. 109-4 at 61.) The Court restates plaintiff's expert's data in the body of the Opinion, but the difference between the two expert reports is inconsequential to the resolution of the parties' motions.

each claim submitted to the government for payment would not have been paid by the government had it known about defendants' false representation that they complied with the AKS. The remedies provision of the FCA supports this view.

The FCA provides, "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1). The term "claim" is defined in relevant part as "any request or demand, whether under a contract or otherwise, for money or property . . . that is presented to . . . the United States." Id. § 3729(b)(2).

Thus, the FCA contemplates that a person violates the FCA each time he knowingly presents a false claim for payment to the government, and that person is liable for at least $5,500

(adjusted from $5,000 for inflation) for each false claim.[14] The FCA does not suggest that one false claim for payment submitted to the government causes all other claims for payment, regardless of whether those other payments were shown to be false, to be violations of the FCA. See, e.g., United States ex rel Doe v. Heart Solution PC, 2016 WL 3647987, at *6 (D.N.J. 2016) (denying defendants' motion to reduce the damages requested by the United States and its qui tam plaintiff: plaintiffs requested $5,006,864.85 in actual damages (three times the $1,668,954.95 that the defendants admitted Medicare paid them for their fraudulent acts), and civil penalties of $2,750,000, because the defendants made at least 500 fraudulent claims to Medicare, and should be penalized at least $5,500 per fraudulent claim, pursuant to 31 U.S.C. § 3729(a)(1)); U.S. v. Bruce, 2013 WL 5780812, at *5 (D.N.J. 2013) (citing S. Rep. No.

[14] In this case, the United States declined to proceed with this action. Where "the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant." 31 U.S.C. § 3730(d)(2).

345, 99th Cong., 2d Sess. 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5273) ("Defendant is liable for $27,021.00 (three times the $9,007.00 he was improperly paid), in addition to a civil penalty between $5,500 and $11,000 (the statutory amount as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, see 28 C.F.R. § 85.3(a)(9)) for each false claim. The legislative history of the 1986 amendments to the FCA makes clear that civil penalties are "automatic and mandatory for each claim which is false." Because of the relatively low total sum of fraudulently paid benefits and the other facts of this case, the Court finds the statutory minimum civil penalty of $5,500 for each false claim appropriate. Defendant is therefore liable to the Government for the sum of $27,021.00 and $82,500 ($5,500 times the fifteen false claims), or a total of $109,521.00."); Coleman v. Hernandez, 490 F. Supp. 2d 278, 281 (D. Conn. 2007) ("Liability attaches for each false claim submitted).

Thus, a defendant is subject to a civil penalty and treble damages on each false claim. United States ex rel. Kreindler & Kreindler v. United Technologies Corp., 985 F.2d 1148, 1157 (2d Cir. 1993) (holding that "the number of assertable False Claims Act claims is not measured by the number of contracts, but

rather by the number of fraudulent acts committed by the defendant") (citing United States v. Ehrlich, 643 F.2d 634, 638 (9th Cir. 1981)) ("[I]f a person knowingly causes a specific number of false claims to be filed, he is liable for an equal number of forfeitures.")); cf. U.S. v. Karron, 750 F. Supp. 2d 480, 494–95 (S.D.N.Y. 2011) ("The Government argues that Karron is subject to penalties for each false report or certification that she made to the Government. The Government further asserts that Karron submitted at least twenty false statements . . . . We are not persuaded that summary judgment is proper at this stage on the issue of civil penalties because the Government has failed to specify the precise aspect of each of the twenty documents that is false. To clarify, the Government has established that Karron made false statements as a general matter and has unquestionably established at least one false statement. And it is certainly plausible that each of [the] twenty documents contains a false statement or certification. However, the Government has yet to establish that its position with respect to each document is not subject to genuine dispute.").

Here, plaintiff has shown that defendants submitted claims to the government for hemophilia products, defendants certified

their compliance with the AKS for those claims,[15] and based on defendants' certification of compliance, the government paid defendants. While accepting for the purposes of resolving the parties' motions the premise that defendants' relationship with HANJ/HSI violated the AKS, these proofs would be sufficient to establish plaintiff's FCA claim, but only if he had also shown that each of defendants' claims to the government for payment was directly linked to defendants' donations to HANJ/HSI. Because plaintiff has not shown the link between defendants' 24 federally insured customers and defendants' donations to HANJ/HSI, plaintiff's FCA claim fails.

On the contrary, the record evidence establishes that each HANJ/HIS related patient was free to make his or her own choices regarding providers. Nor did HANJ/HIS refer patients to the providers it endorsed for any particular or specific services. Simply listing Accredo, among other providers, as "preferred" and acknowledging their contributions to HANJ/HIS's state-approved - even state encouraged – charitable activities, is too attenuated a causal connection. Absent some evidence, any

[15] Defendants argue that certain forms they submitted to the government for payment of several claims did not require certification of their compliance with the AKS. The Court does not need to address that argument.

evidence, that those particular patients chose Accredo because of its donations to HANJ/HIS, Plaintiff cannot carry his burden on an essential element of his claim.

CONCLUSION

For the reasons expressed above, plaintiff's motion for summary judgment will be denied, and defendants' motion for summary judgment will be granted. An appropriate Order will be entered.

Date: December 22, 2016
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.